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16955DIVCONCIPCON(AP) #31
PATENT 7/31/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of

Woodward et al

Serial No: 08/876,937
Conf. No. 5537
Filed: June 16, 1997

For: NON-ACIDIC CYCLOPENTANE HEPTANOIC ACID, 2-CYCLOALKYL OR ARYLALKYL DERIVATIVES AS THERAPEUTIC AGENTS

Group Art Unit: 1621

Examiner: P. O'Sullivan

Commissioner for Patents
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Dear Sir:

This appeal is taken from the final rejection claims 26 through 45 in an Examiner's action mailed January 15, 2003. Oral hearing is waived.

(1) REAL PARTY IN INTEREST

This patent application is assigned to Allergan, Inc., having its principal place of business at 2525 Dupont Drive, Irvine, CA 92612.

(2) RELATED APPEALS AND INTERFERENCES

None.

(3) STATUS OF CLAIMS

Claims	Status

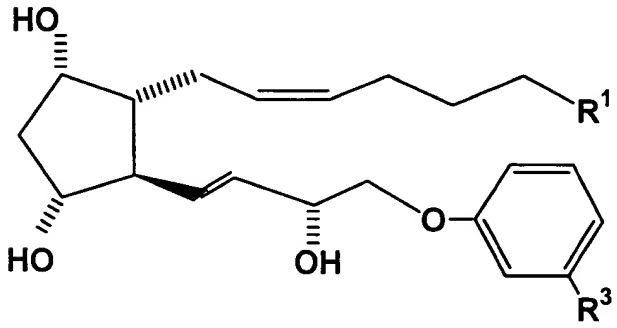
26 through 45	Rejected under 35 USC § 102(e) as being anticipated by Bishop '383.
26 through 45	Rejected under 35 USC § 103(a) as being unpatentable over Bishop '383.

(4) STATUS OF AMENDMENTS

No amendment or other responses were filed after the Final Rejection.

(5) SUMMARY OF THE INVENTION

The present invention provides a method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of a compound of formula:



wherein R^1 =hydrogen, a cationic salt moiety, a lower alkyl and R^2 = Cl or CF_3. (See claim 26.) Topical ophthalmic compositions useful in the method of the invention are also provided. (See claim 34.)

Claims 46 and 47 to the use of cloprostenol and fluprostenol, respectively, in treating glaucoma and ocular hypertension have been allowed but are subject to an interference. (Claim 48 is assumed to be allowed at it is similar in scope to claim 46.)

Claims 28 and 36 have been cancelled. (See Amendment mailed October 29, 2002.)

(6) ISSUES

Anticipation

Whether claims 26-45 lack novelty over United States Patent Number 5,510,383 to Bishop et al (Bishop '383)?

Obviousness

Whether claims 26-45 are obvious over Bishop '383?

(7) GROUPING OF CLAIMS

Group II, Anticipation includes claims 26 through 45.
Group III, Obviousness includes claims 26 through 45

(8) ARGUMENT

ANTICIPATION

(iii) The Rejection of Claims 26-45 under 35 USC § 102(e).

The Examiner has rejected claims 26-45 under 35 USC § 102(e) as being anticipated by Bishop et al. (As noted above, claims 28 and 36 have been cancelled.) As stated above, claims 26-45 of this application had been copied from U.S. Patent 5,510,383, i.e. Bishop et al, to provoke an interference. (Claims 26-45 were first copied in U.S. Patent Application Serial No. 08/605,567, the parent of the present application, which has a filing date of February 22, 1996, i.e. earlier than the April 23, 1996, issue date of Bishop

et al.) The claims originally copied have been amended to limit R^1 to hydrogen, a cationic salt moiety or a lower alkyl. The claims, as amended, are no longer rejected under 35 USC § 112. (See the Final Rejection of January 15, 2003.)

The Examiner rejected Claims 26-45 under 35 USC § 102(e) as being anticipated by Bishop et al which discloses and claims the use of cloprostenol, fluprostenol, etc. to treat glaucoma and ocular hypertension. (See the Title of Bishop et al.)

The applicants wish to point out that pending claims 26 through 45 are supported in U.S. Patent Application 07/948,056, the Grandparent of the present Application having a filing date of September 21, 1992 (which predates the filing date of Bishop '383) as follows:

It is clear that the applicants disclose in the Grandparent Application, the compound 16-m-chlorophenoxy $PGF_{2\alpha}$, i.e. cloprostenol which is the corresponding acid of the isopropyl ester designated as A in Table 1 of Bishop '383. (The acid, i.e. cloprostenol, is included in claim 1 of Bishop '383, i.e. where R^1 is hydrogen and R^2 is chlorine.) This compound is also shown at Table V of the Grandparent Application to be an effective IOP lowering agent both as an acid and as the 1-hydroxyl and 1-amido derivatives thereof. Note the methyl ester and the amido derivatives of 16-m-chloro phenoxy $PFG_{2\alpha}$, i.e. cloprostenol, are prepared in Examples 8 and 9 of the Grandparent Application while the 1-hydroxy derivative is prepared in Example 15 of the Grandparent Application. (The preparation of the methyl ester of cloprostenol argues against Examiner's assertion in the Final Rejection that

Bishop "discloses specific ester compounds not disclosed in Woodward '708", i.e. the Grandparent.")

The applicants also submitted a Declaration Under Rule 1.131 in the '567 Application which demonstrates that, prior to the filing date of Bishop '383, the applicants had reduced to practice the present invention as related to fluprostenol in the United States." (A copy of the Declaration under 37 CFR § 1.131 was filed in the present application for the Examiner's reference.) Fluprostenol is the corresponding acid of the isopropyl ester designated as B in Table 1 of Bishop et al and is also included in claim 1 of Bishop '383, when R^1 is hydrogen and R^2 is CF_3.

Thus, as to the compounds upon which the invention of Bishop '383 is based, i.e. cloprostenol and floprostenol, applicants have either an earlier filing date or declaration showing a reduction to practice prior to the filing date of Bishop '383. The further disclosure of Bishop '383, that the acids cloprostenol and fluprostenol may be esterified or converted to a pharmaceutically acceptable salt for the purpose of treating glaucoma or ocular hypertension may be shown to be obvious in view of applicants showing of the same activity for said acids.

Furthermore, applicants believe that under 35 USC § 102(g) Bishop's claims may not be patentable since applicants believe that they may be able to show that the invention of Bishop "was made in this country by another", i.e. Woodward et al, prior to the date of invention by Bishop. The Declaration under 35 USC § 131 was filed to show Woodward et al made the invention before Bishop et al's filing date. The Board is referred to Bates v. Coe 98 U.S. 31, 34 (1878) wherein it is stated that "the presumption in respect to the invention described in the patent in suit, if

it is accompanied by the application for the same, is that it was made at the time the application was filed; and the complainant or plaintiff may, if he can, introduce proof to show that it was made at a much earlier date."

Thus, for two reasons, the Examiner is incorrect in his rejection under 35 USC § 102(e):

First, applicants are entitled to prove in an interference that they are the prior inventors and entitled to a patent on the invention defined in claims 26 through 45.

Second, the patentees, i.e. Bishop et al, may not be entitled to the patent under 35 USC § 102(g) since they were not the first to make the invention.

OBVIOUSNESS

(iv) The Rejection of the Claims 26-45 under 35 USC § 103. For reasons given above regarding the Examiner's rejection of claims 26-45 as anticipated by Bishop et al, it is believed that the applicants disclosed the subject matter of such claims prior to Bishop et al. Therefore, it is believed that the claims are not properly rejected over Bishop et al under 35 USC § 103.

In view of the above, the Board is asked to reverse the Examiner's holding of all of the pending claims as unpatentable and direct the Examiner to pass the claims to issue.

Respectfully submitted,

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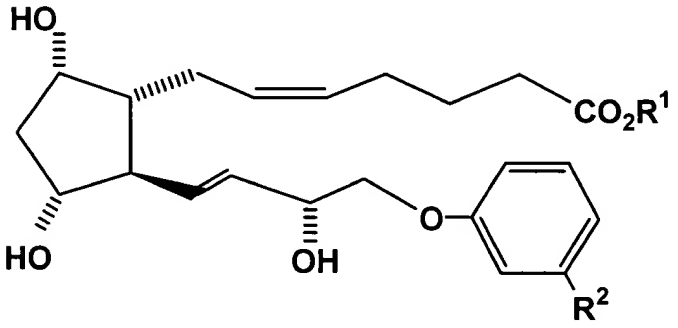
CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST-CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP APPEAL BRIEF COMMISSIONER FOR PATENTS, ALEXANDRIA, VA 22313-1450 ON 7/18/03 Printed name of person making deposit: Bonnie Ferguson Signature of person making deposit: Bonnie Ferguson
Date Signed: 7/18/2003

(7) APPENDIX

CLAIMS:

26. A method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of a compound of formula:



wherein R^1 = hydrogen, a cationic salt moiety, a lower alkyl; and R^2 = Cl or CF_3.

27. The method of claim 26, wherein R^1 is selected from the group consisting of H, CH_3, $CH(CH_3)_2$ and $C(CH_3)_3$.

29. The method of claim 26, wherein R^2 is Cl.

30. The method of claim 27, wherein R^2 is CF_3.

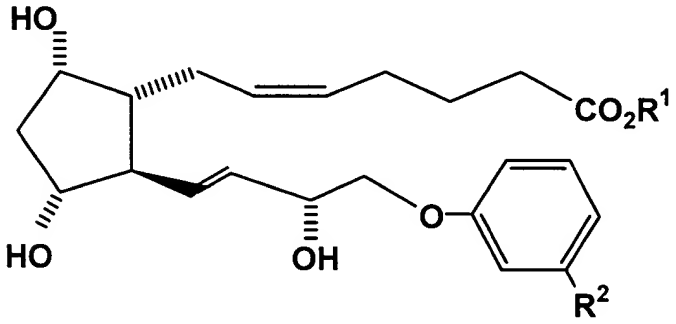
31. The method of claim 26, wherein between about 0.001 and about 1000 µg/eye of a compound of formula (I) is administered.

32. The method of claim 31, wherein between about 0.01 and about 100 µg/eye of a compound of formula (I) is administered.

(7) APPENDIX (Cont.)

33. The method of claim 31, wherein between about 0.05 and about 10 μg/eye of a compound of formula (I) is administered.

34. A topical ophthalmic composition for the treatment of glaucoma and ocular hypertension in primates, comprising topically a therapeutically effective amount of a compound of formula:



wherein R^1 = hydrogen, a cationic salt moiety, or a lower alkyl; and R^2 = Cl or CF_3.

35. The composition of claim 34, wherein R^1 is selected from the group consisting of H, CH_3, $CH(CH_3)_2$ and $C(CH_3)_3$.

37. The composition of claim 34, wherein R^2 is Cl.

38. The composition of claim 34, wherein R^2 is CF_3

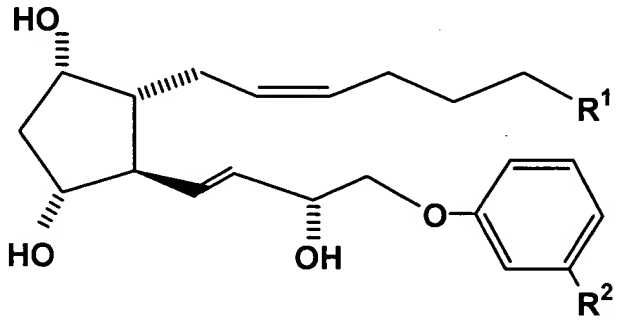
39. The composition of claim 34, wherein between about 0.001 and about 100 μg/eye of a compound of formula (I) is administered..

(7) APPENDIX (Cont.)

40. The composition of claim 39, wherein between about 0.01 and about 100 μg/eye of a compound of formula (I) is administered.

41. The composition of claim 40, wherein between about 0.05 and about 10 μg/eye of a compound of formula (I) is administered.

42. A method of treating glaucoma and ocular hypertension, which comprises topically administering to the affected eye a therapeutically effective amount of a compound of formula:



wherein R^1 = a pharmaceutically acceptable lower alkyl ester moiety; and R^2 = Cl or CF_3.

43. The method of claim 42, wherein R^2 is Cl.

44. The method of claim 42, wherein R^2 is CF_3.

45. The method of claim 42, wherein between about 0.001 and about 1000 μg/eye of a compound of formula(I) is administered.

(7) APPENDIX (Cont.)

46. A method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of cyclopentane heptenoic acid, 5-cis-2-(3-α-hydroxy-4-m-chlorophenoxy-1-trans-butenyl)-3,5-dihydroxy 1_{α}, 2_{β}, 3_{α}, 5_{α}].

47 A method of treating glaucoma and ocular hypertension which comprises topically administering to the affected eye a therapeutically effective amount of fluprostenol.

48 A topical ophthalmic composition for the treatment of glaucoma and ocular hypertension in humans, comprising a therapeutically effective amount of fluprostenol.